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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/995,081 | 11/27/2001 | David J. Steklenski | 83760D-W | 9563 |

7590 02/27/2004

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EXAMINER

PAIK, STEVE S

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

2876

DATE MAILED: 02/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/995,081

Applicant(s)

STEKLENSKI ET AL.

Examiner

Steven S. Paik

Art Unit

2876

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2003.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-26 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-10 and 12-26 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/16/2003.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Receipt is acknowledged of the Amendment filed October 22, 2003. The Amendment includes cancellation of claim 11 and addition of claims 17-26.

Claim Objections

2. Claims 17-16 are objected to because of the following informalities: The independent claim recites the limitation of "a first region capable of..." in line 5. The phrase, "capable of" fails to claim the invention clearly and definitely. The dependent claims 18-26 are also objected because the claims are dependent claims of Claim 17. It is respectfully suggested to replace the phrase with a word -- for -- to define the invention in a more precise manner. Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-10, 12-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kirollos et al. (US 6,284,198) in view of Morita et al. (US 4,668,714).

Re claims 17-26, Kirollos et al. disclose a self-appearing warning sign device and a method for using the sign device which functions as a colorimetric dosimeter for visual or electronic detection or which functions as a warning label or tag for indicating exposure to radiation. The dosimeter comprises a support (a s plastic non-reacting support substrate 4), at

Art Unit: 2876

least one first region (indicating layer 2) disposed (coated or printed) on said support (col. 4, ll. 35-39, at least one second region (protective screen 6) disposed on said support (col. 5, ll. 5-10) where the first region is capable of measuring an absorbed dose of ionizing radiation and the second region bears an identification mark (8; col. 6, ll. 5-25) on a substrate. The identification mark generates a warning by changing colors when exposed to radiation. Furthermore, the indicating layer is covered with a screen(s) permeable or semi-permeable to light, gas and vapor diffusion. Figs. 13a-13j shows exemplary symbols including alphanumeric characters and symbols.

However, Kirollos et al. lack the specific teachings of the first region containing alanine and a binder.

Morita et al. disclose an alanine dosimeter that enables accurate and simple measurement of an absorbed dose of an ionizing radiation. Morita et al. teach that when the crystal of alanine, an amino acid, is irradiated with a radiation, it produces stable and characteristic radicals in precise proportion to the dose absorbed by the crystal. The radicals formed by irradiation with radiation remain stable within the crystal of alanine and their concentration is subjected to a very small degree of time-dependent change. Furthermore, radicals formed in the crystal of alanine are fairly stable against heat. The rubber and alanine crystal are mixed between a lower and upper limit to produce a uniform composition of rubber and alanine. Therefore, a dosimetry with high precision and reproductivity can be performed (col. 1, ll. 57+ and col. 2, ll. 1-9). Along with the disclosed advantages of alanine crystal, Morita et al. suggest using a binder agent (synthetic or natural rubber) that produces a very small amount of radicals upon exposure to

Art Unit: 2876

radiation and or that has its heat resistance improved by cross-linking treatment (col. 3, ll. 27-33).

In view of Morita et al. teaching, it would have been obvious to an artisan of ordinary skill in the art at the time the invention was made to further employ a dosimeter containing a rubber as a binder agent and crystalline alanine in addition to the colorimetric dosimeter for indicating exposure to radiation, as taught by Kirolos et al. since more flexible (rubber) and stable for long periods of time dosimeter can be produced on the support for the purposes of measuring the amount of absorbed radiation precisely and efficiently (col. 7, ll. 6-25 and col. 7, 1-25). Furthermore, such modification of employing a dosimeter using a binder agent such as a synthetic or natural rubber to the teachings of Kirolos et al. would have been an obvious matter of design variation, well within the ordinary skill in the art, and therefore an obvious expedient.

Re claim 15, Kirolos et al. disclose a device and a method for measuring an absorbed dose of ionizing radiation using a colorimetric dosimeter including, among other things, a first region, a second region and a support.

Although Kirolos et al. disclose, teach, or fairly suggest a method of measuring an absorbed dose of ionizing radiation, the reference does not specifically disclose the size of crystalline alanine comprising particle less than 100 microns in size.

Morita et al. disclose an alanine dosimeter that enables accurate and simple measurement of an absorbed dose of an ionizing radiation. The radicals formed by irradiation with radiation remain stable within the crystal of alanine and their concentration is subjected to a very small degree of time-dependent change. The rubber and alanine crystal are mixed between a lower and

Art Unit: 2876

upper limit to produce a uniform composition of rubber and alanine. Morita et al. further disclose that the power is so fine without disclosing a specific size of the particle.

Hence, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to select a predetermined size of a crystalline alanine particle, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). The fine crystal of alanine mixed with a binder agent such as rubber provides uniformly dense dosimetry.

Re claim 16, Kirolos et al. in view of Morita et al. disclose the method as recited in rejected claim 11 stated above, where the coated first region (indicating layer 2) is between 100 and 200 microns (2 mm) thick (col. 3, ll. 4-10).

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 17-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 and 10 of copending Application No. 09/995,088. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed features in the independent claim is

Art Unit: 2876

identical with the exception of the features recited in the wherein clause and the dependent claims are identical.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

7. Applicant's arguments with respect to claims 1-16 have been considered but are moot in view of the new ground(s) of rejection.

Upon careful review of the applicants' argument and the amended claims, the examiner has updated the prior art search and found another prior art. The amended claims and newly added claims are now rejected in view of the new ground of rejection as set forth in this Office Action.

Therefore, claims 1-10 and 12-26 are rejected under 35 U.S.C. §103 (a) or provisional obviousness-type double patenting rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Art Unit: 2876

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven S. Paik whose telephone number is 571-272-2404. The examiner can normally be reached on Mon - Fri (5:30am-2:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Lee can be reached on 571-272-2398. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0530.



Steven S. Paik
Examiner
Art Unit 2876

ssp
February 2, 2004



MICHAEL G. LEE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2800